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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d18646

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 1998

WARNING LETTER

VIA FEDERAL EXPRESS

Ref:OC:I1-1780

Mr. Stephen Hsu
U.S. Agent
Compliance Engineering Service, Inc.
1366 Bordeaux Drive
Sunnyvale, California 94089

Mr. Stephen Hu
Safety Engineer
Fan Shaing Electronics Co., Ltd.
54, Wu-Chuang Road
Wu-Ku, Taipei Hsien, TAIWAN
REPUBLIC OF CHINA

Dear Mr. Hsu and Mr. Hu:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), hereby disapproves the quality control and testing program for Fan Shaing Electronics Co., Ltd. of Taiwan. This action is taken under the authority of the United States' (U.S.) Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control.

Based on the findings listed below, CDRH has concluded that Fan Shaing Electronics Co., Ltd. has failed to conduct a testing program which assures compliance with the applicable performance standard. Under the authority of 534(h) of the Act and 21 Code of Federal Regulations (CFR) 1010.2(c), CDRH hereby disapproves the testing program for all television products at Fan Shaing Electronics Co., Ltd., effective immediately.

CDRH's disapproval of your testing program is based on the apparent fraudulence of the two calibration certificates for the x-radiation survey instruments, particularly the Wm. B. Johnson TVX-1B, and the Victoreen 440 RF/D. The apparent fraudulence of the two certificates was discovered during the review of two Fan

Shaing Electronics Co., Ltd. product reports submitted to CDRH, for chassis family F-1450A, dated September 9, 1997, and chassis family F-14N, dated January 12, 1998.

The x-radiation survey instruments described in the product reports are primarily used for detection and measurement of x-radiation from completed television/computer monitor products. Manufacturers of television/computer monitor products are required to have in place an overall quality control and testing program, which should include the ability to conduct x-radiation measurements using calibrated survey meters (qualitative and quantitative). The intent of the instrumentation and calibration program is to assure that completed television/computer monitor products will comply with the emission requirements of the Federal Performance Standard for Television Receivers, 21 CFR 1020.10. Moreover, for every product report filed with CDRH in accordance with the instructions written in the CDRH's Reporting and Compliance Guide For Television Products, the manufacturer must submit Part 6.15 Production X-Radiation Test Instruments Identification and Calibration, describing the instruments used in x-radiation testing of completed products, and submit Attachment M - Calibration Certificate for the Quantitative Meter Showing Current Calibration.

During its review of Fan Shaing Electronics Co., Ltd.'s product reports, CDRH discovered apparent fraud in the following two documents:

1. The product report for chassis family F-1450A contained a copy of the certificate of calibration for the qualitative Wm. B. Johnson TVX-1B x-radiation survey meter, serial number 8416, which showed a calibration date of 7/24/97 (see exhibit 1). The other product report for chassis family F-14N, contained a copy of the Wm. B. Johnson TVX-1B certificate of calibration for a different meter, serial number 9817, and a calibration date of 11/13/97 (see exhibit 2). During the review of these certificates, CDRH discovered that an instrument with serial number 9817 does not exist.

2. The product report for chassis family F-1450A contained a copy of the calibration certificate for the quantitative Victoreen 440 RF/D, x-radiation survey meter, serial number 1133, which showed a calibration date of "19-Dec-96" (see exhibit 3).

The latest calibration certificate, dated "19-Dec-97," appeared to have been altered to show current calibration for the Victoreen 440 RF/D survey meter (see exhibit 4).

Since the two product reports contained apparently fraudulent information concerning the instruments used in x-radiation testing, CDRH cannot be assured of the proper certification of the products. Therefore, CDRH has concluded that Fan Shaing Electronics Co., Ltd.'s quality control and testing program is not adequate to assure compliance with the Federal performance standard for television products.

You should be aware that it is a prohibited act under Sections 534(h) and 538(a)(5)(B) of the Act for any person "... **to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.**"

The FDA may initiate regulatory action against any person who violates Section 538, including an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

This Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) or to furnish or preserve any information required pursuant to Section 537(f).

Moreover, under Section 536(a) of the Act, FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

Therefore, Fan Shaing Electronics Co., Ltd. is being placed on the import detention list and its products will be automatically detained until the quality control and testing program disapproval is rescinded.

Under 21 CFR 1005.21 and Section 536 of the Act, the manufacturer shall have an opportunity to present views and evidence that the products comply with the Federal Performance Standard for Television Products, 21 CFR 1020.10.

Under 21 1002.10, manufacturers must submit to CDRH a product report containing the information specified in 21 CFR 1002.10(a)-(j). In addition, CDRH may require other information reasonably necessary to establish the product's compliance with the law and to enable CDRH to carry out the purposes of the Act. Under 21 CFR 1002.10(k), CDRH requests the following additional information:

1. The manufacturer is to provide CDRH with a video tape of the Phase III x-radiation testing procedures, including (a) equipment set-up (volt meter, ammeter, input line voltage meter, etc.), the x-radiation survey meters (Wm. B. Johnson TVX-1B, and Victoreen 440 RF/D), (b) actual procedures performed on a television receiver or monitor including worst component failure selected for the test, user and service controls to be adjusted, test pattern used, measurement of high voltage and beam current, B plus, operational checks of hold-down safety circuit, daily operational check and correct handling of the qualitative and quantitative x-radiation survey meters, scan patterns, data to be noted and recorded on the final test record, tolerances and rejection limits, and procedures to be followed in case any reading is out of tolerance or over the limit.

   Step-by-step instructions during Phase III x-radiation testing must be open captioned in English on the video tape.

2. The manufacturer's quality control and testing program must be inspected by an independent consultant or a firm who will observe the actual quality control and testing procedures and compare with those reported in the product report. This independent inspection report should be furnished along with any response concerning this program disapproval.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may resume. In addition, Fan Shaing Electronics Co., Ltd. must advise CDRH in writing of the total number of Model F-1450A and F-14N sets produced and the number of products introduced into U.S. commerce, as required under 21 CFR 1003.11.

A copy of this letter will be posted on the FDA's world wide web home page under Monthly Import Detention List and Warning Letters: http://www.fda.gov.

Within 15 days, please submit your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, (HFZ-342), Division of Enforcement III, 2098 Gaither Road, Rockville, Maryland 20850. In your response, please reference case I1-1780. If you have any questions, you may contact Mr. George W. Kraus of my staff at (301) 594-4654 or by facsimile at (301) 594-4672.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures:

Exhibit 1: Wm. B. Johnson & Associates, Inc. certificate of calibration, TVX-1B, for serial number 8416, dated 7/24/97 - taken from Fan Shaing Electronics Co., Ltd. product report, dated September 9, 1997, accession number 9721593.

Exhibit 2: Wm. B. Johnson & Associates, Inc. certificate of calibration, TVX-1B, for serial number 9817, dated 11/13/97 - taken from Fan Shaing Electronics Co., Ltd. product report, dated January 12, 1998, accession number 9820046.

Exhibit 3: Victoreen 440 RF/D calibration certificate for Model 440 RF/D, serial number 1133, dated 19-Dec-96 - taken from Fan Shaing Electronics Co., Ltd. product report, dated September 9, 1997, accession number 9721593.

Exhibit 4: Victoreen 440 RF/D calibration certificate for Model 440 RF/D, serial number 1133, dated 19-Dec-97 - taken from Fan Shaing Electronics Co., Ltd. product report, dated January 12, 1998, accession number 9820046.